AUG 2 0 2003

K032132 P3 1/1

510(k) Summary of Safety and Effectiveness

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Application Information:

Date Prepared:	February 3, 2003
Submitter:	TissueLink Medical Inc.
Address:	One Washington Center Suite 400 Dover, NH 03820
Contacts:	Vicki S. Anastasi Directory Regulatory Affairs
Telephone Number:	(508) 922-1622
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	Roberta L. Thompson Vice President, Clinical, Regulatory and Quality
Telephone Number:	(603) 742-1515 ext. 106
Fax Number:	(603) 742-1488

Device Information:

Trade Name:	TissueLink Bipolar Sealer 2.3 (Bipolar Floating Ball) device
Common Name:	Electrosurgery Bipolar Sealer
Classification Name:	Electrosurgical cutting and coagulation device and accessories, 21CFR 878.4400

Predicate Devices:

Claim of Substantial Equivalence of the TissueLink Bipolar Floating Ball (Bipolar Sealer 2.3) device is made to:

TissueLink Bipolar Floating Ball

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 0 2003

Ms. Vicki S. Anastasi
Director Regulatory Affairs
TissueLink Medical, Inc.
One Washington Center, Suite 400
Dover, New Hampshire 03820

Re: K032132
Trade/Device Name: TissueLink Bipolar Sealer 2.3 (Bipolar Floating Ball) device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: July 11, 2003
Received: July 28, 2003

Dear Ms. Anastasi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for use Statement

Page ____ of ____

510(k) Number (if known): K032132

Device Name: TissueLink Bipolar Sealer 2.3 (Bipolar Floating Ball) device

Indications for Use:

The TissueLink BPS bipolar sealer is a sterile, single use electrosurgery device intended to be used in conjunction with an electrosurgical generator for delivery of radiofrequency current and saline for hemostatic sealing and coagulation of soft tissue and bone at the operative site. It is intended for, but not limited to, endoscopic and open abdominal, orthopaedic, spine and thoracic surgery. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109) Optional Format 1-

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032132